EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
Establishment of Control Numbers and Tracking Laboratory Supplies

SOP Number: QC-09-02

Date Revised: 08-28-02

Prepared By: _____ Date: ___/___/___

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Reviewed By: _____ Date: ___/___/___

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Print Name:_____
QA Officer

_____ Date: ___/___/___

Print Name:_____
Laboratory Director

Date Issued: ___/___/___

Withdrawn By: _____ Date: ___/___/___

Controlled Copy No.: _____

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1.0 SCOPE AND APPLICATION:

1.1 Tracking supplies from date of receipt is an essential quality control practice. This protocol describes the methods used to establish the control numbers for tracking chemicals, media, reagents and laboratory materials.

2.0 DEFINITIONS:

2.1 MSDS = Material and Safety Data Sheets

2.2 OMLIMS = OPP Microbiology Laboratory Information Management System

3.0 HEALTH AND SAFETY:

3.1 Acid, bases and volatile chemicals should be handled according to the manufacturer's instructions or information stated in the MSDS.

4.0 CAUTIONS: None

5.0 INTERFERENCES:

5.1 All chemicals, media and reagents must have an identified and legible control number in order to be used by the laboratory.

5.2 All attempts must be made to identify the control number of a chemical, media or reagent through vendor packing slips.

5.3 If a control number cannot be identified for a particular chemical, media or reagent, then the item is discarded.

6.0 PERSONNEL QUALIFICATIONS:

6.1 Personnel are required to be knowledgeable about and to comply with the laboratory's record keeping procedures. Documentation of training and familiarization with these requirements can be found in the training file for each employee.

7.0 SPECIAL APPARATUS AND MATERIALS:

7.1 All chemicals, media or reagents will be handled, used and stored according to the manufacturer's recommendations or information provided in the MSDS form.

7.2 The OMLIMS is written in Oracle Forms Version 5.0.6.8.0 and Oracle Reports Version 3.0.5.8.0 with the data stored in an Oracle database which resides on the Office of Pesticide Programs' Oracle server in Crystal City, VA.

8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable

9.0 SAMPLE HANDLING AND STORAGE:

9.1 Acids, bases, flammable, or volatile chemicals or reagents will be handled and stored in the appropriate cabinet or refrigerator according to the manufacturer's recommendation or as noted in the MSDS.

10.0 PROCEDURE AND ANALYSIS:

10.1 All chemicals, media, prepared or purchased reagents, test kits, organisms, and pre-sterilized laboratory supplies will be logged into the OMLIMS upon receipt and assigned a control number. The OMLIMS is used to track supplies and contain important information such as vendor, catalog number, lot number, control number, expiration date, sterility requirements, storage conditions and supply status (Full, In Use, Discarded or Expired) (see 16.1). The products are marked with a label containing the control number. The date the product was opened will be indicated on all chemicals, media or purchased reagents. This information should be clearly legible on the labeled container.

10.2 The control number consists of three parts: 1) the first seven digits represent the date the product was received: RMMDDYY where R= received, MM=month, DD= day, and YY=the last two digits of the calendar year; 2) the next seven digits represent the expiration date of the product: EMMDDYY where E=expiration, MM=month, DD=day, and YY=the last two digits of the calendar year; and 3) the suffix where the digits after the dash act as a counter for the number of products received on the same date. For example, the first product received and logged in on 03-10-02 with an expiration date of 12-2004 (no day given) would have the control number R031002E120004-01. The next item received on

that same day would have a suffix of -02; the third item received would have a suffix of -03; etc. If multiple items of the same product are received on the same day, an upper case alphabetical character is added to the suffix to differentiate the items: i.e., if the first product received on 03-10-99 consisted of three identical containers of dehydrated media X, same lot and expiration number, the control numbers assigned would be R031099E120002-01A, R031099E120002-01B, and R031099E120002-01C. If a product does not have an expiration date, E000000 should be used for that part of the control number.

11.0 DATA ANALYSIS/CALCULATIONS: None

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 Data will be recorded promptly in the OMLIMS. Monthly reports (see 16.2) are printed and archived in notebooks kept in locked file cabinets in the file room D217. Only authorized personnel have access to the locked files. Archived data is subject to OPP's official retention schedule contained in SOP ADM-03, Records and Archives.

13.0 QUALITY CONTROL:

13.1 The OPP Microbiology Laboratory conforms to 40 CFR Part 160, Good Laboratory Practices. Appropriate quality control measures are integrated into each SOP.

13.2 For quality control purposes, the required information is documented in the OMLIMS (see 16.1).

13.3 A report is run weekly which identifies supplies by control number that have expired so that they will be discarded (see 16.3).

13.4 A second report is run weekly which identifies supplies by control number that will expire in the next 30 days in order to help identify supply items that may have to be ordered to keep the supply item in stock when existing stock expires (see 16.4).

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 If a chemical, media or reagent is discovered to have no control number,

an attempt should be made using vendor “packing slips” and other information to identify the date the product was received. If a date received is established, assign a control number to it using this information; the appropriate suffix to be assigned is based on the sequence for that date.

14.2 If the exact date received cannot be established, but the month and/or year is known, use this information to establish a control number for the product, filling in with zeros for the unknown information and using “XX” for the suffix (e.g., R060002E120004-XX).

14.3 If no date received information is available, the product may be used if it is labeled with an expiration date. In this case, a control number is assigned (e.g., R000000E120004-XX) and the product may be used until the expiration date.

14.4 If no date received or expiration date can be determined, the product is discarded.

15.0 REFERENCES: None

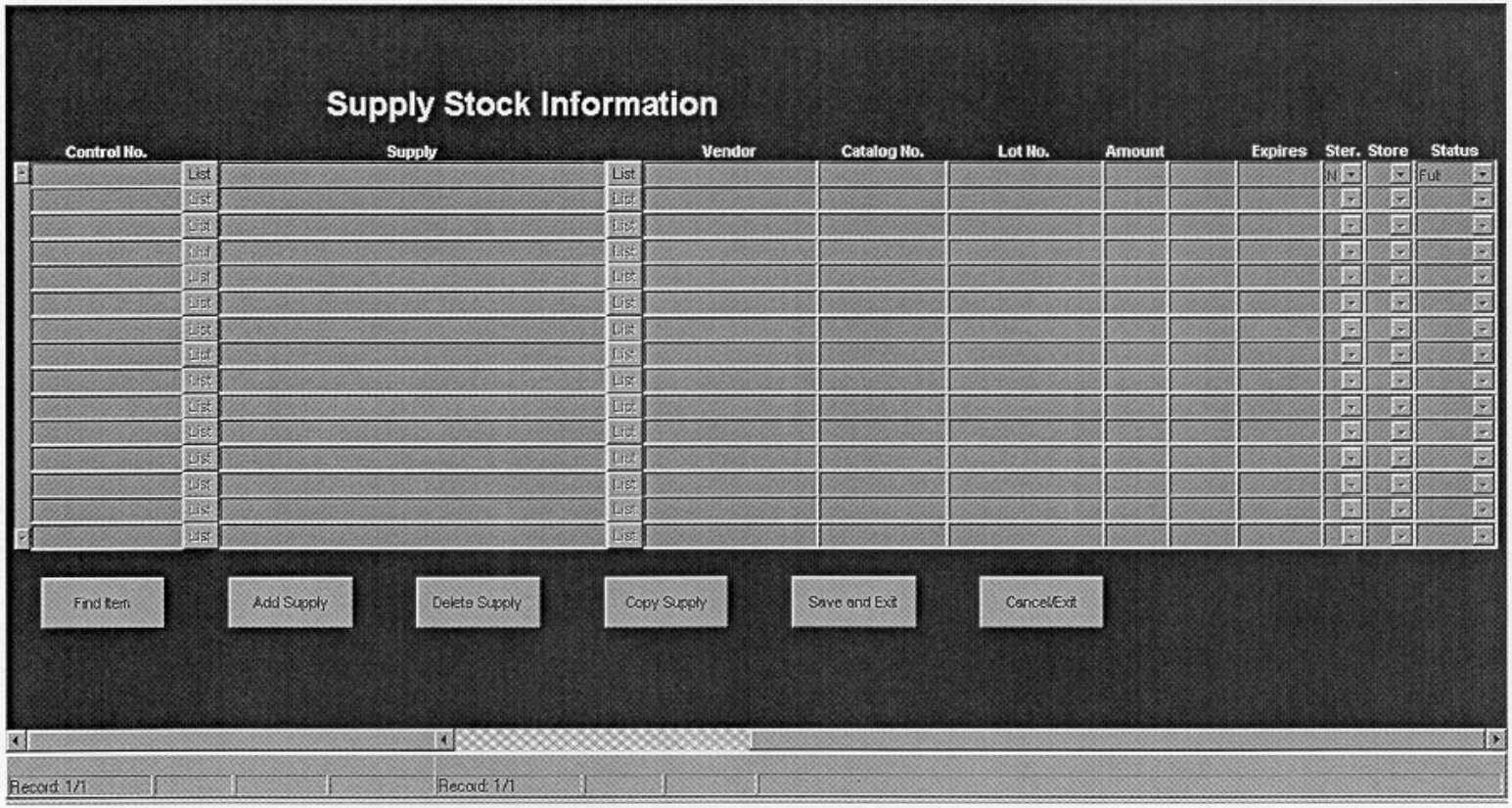
16.0 FORMS AND DATA SHEETS:

16.1 Supply Stock Information (OMLIMS)

16.2 Laboratory Supplies Received Report

16.3 Laboratory Supplies Which Expired On or Before a Particular Date

16.4 Laboratory Supplies Which Will Expire Within 30 Days of a Particular Date


Supply Stock Information
Control No.
Supply
Vendor
Catalog No.
Lot No.
Amount
Expires
Ster.
Store
Status
List
Find Item
Add Supply
Delete Supply
Copy Supply
Save and Exit
Cancel/Exit
Record: 1/1
Record: 1/1

OPP Microbiology Laboratory Supplies Received During Mar. 2002

14-Mar-02

Control No.	Supply Name	Vendor	Catalog No.	Lot No.	Sterility	Storage

Storage: RF = Refrigerator; FR = Freezer; RT = Room Temperature

OPP Microbiology Laboratory Supplies Which Expired On or Before the Week of Mar. 14, 2002

14-Mar-02

Control No.	Supply Name	Vendor	Catalog No.	Lot No.	Sterility	Storage

Storage: RF = Refrigerator; FR = Freezer; RT = Room Temperature

OPP Microbiology Laboratory Supplies Which Will Expire Within 30 Days after Mar. 14, 2002

14-Mar-02

Control No.	Supply Name	Vendor	Catalog No.	Lot No.	Sterility	Storage

Storage: RF = Refrigerator; FR = Freezer; RT = Room Temperature